REMARKS

Entry of the foregoing amendments is respectfully requested.

Summary of Amendments

Upon entry of the foregoing amendments, claims 1-13 and 15-26 are cancelled and claims 27-55 are added, whereby claims 27-55 will be pending, with claims 27, 40 and 45 being independent claims. Support for the amended and new claims can be found throughout the present specification (see in particular, pages 3, 18, 19 and 35 as well as the Examples) and the original claims. Regarding claims 28, 40 and 46, Example 7 and the results listed in Table 2 may, for example, be referred to.

Applicants emphasize that the cancellation of claims 1-26 is without prejudice or disclaimer, and Applicants expressly reserve the right to prosecute these claims in one or more continuation and/or divisional applications.

Summary of Office Action

As an initial matter, Applicants note that the obviousness-type double patenting rejection over the claims of U.S. application 10/735,310 set forth in the previous Office Action has been withdrawn.

Claims 1, 2, 5-12, 16 and 26 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP 0 212 681 (hereafter "EP'681").

Claims 1, 2, 5-8, 10-12, 16 and 26 stand rejected under 35 U.S.C. § 103(a) as

allegedly being unpatentable over U.S. Patent No. 4,839,174 to Baker et al. (hereafter "BAKER").

Claims 1, 3, 6-10, 12, 16-20, 23, 24 and 26 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,958,447 to Haralambopoulos et al. (hereafter "HARALAMBOPOULOS").

Claims 3, 4 and 17-25 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681 in view of U.S. Patent No. 4,915,950 to Miranda et al. (hereafter "MIRANDA").

Claims 11-15 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681 in view of U.S. Patent No. 6,419,935 to Gueret (hereafter "GUERET").

Claims 3, 4, 9, 10 and 17-25 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BAKER in view of MIRANDA.

Claims 13-15 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BAKER in view of GUERET.

Claims 2, 4 and 21 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over HARALAMBOPOULOS in view of MIRANDA.

Claims 5, 11, 12 and 22 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over HARALAMBOPOULOS in view of U.S. Patent No. 5,844,013 to Kenndoff et al. (hereafter "KENNDOFF").

Claims 13-15 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over HARALAMBOPOULOS in view of GUERET.

Response to Office Action

Withdrawal of the rejections of record is respectfully requested in view of the foregoing amendments and the following remarks.

Response to Rejection under 35 U.S.C. § 103(a) over EP'681

Claims 1, 2, 5-12, 16 and 26 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP'681 for the reasons set forth in the previous Office Action.

Applicants respectfully disagree with the Examiner in this regard. In particular, it is pointed out that both the cancelled claims and the claims submitted herewith recite that the matrix of the present invention is self-adhesive. EP'681 neither teaches nor suggests a self-adhesive matrix and for this reason alone, is unable to render obvious the subject matter of any of the claims submitted herewith.

Specifically, that the matrix of the drug releasing member of the drug release system of EP'681 is not self-adhesive is apparent from the fact that the drug releasing member of the patch of EP'681 is used in combination with a pressure sensitive adhesive, which clearly indicates that the drug releasing member itself lacks self-adhesiveness.

For example, in the paragraph bridging columns 5 and 6 of EP'681 it is stated with reference to the drawing that "the preferred embodiment of the drug release system of the present invention is a medical patch 10 comprising successive layers of an oxygen and water vapor permeable polyurethane substrate 12, a pressure sensitive adhesive 14, and the above-described drug releasing member 16. The medical patch may optionally be provided with a second layer of adhesive 18 on the exposed side of the drug releasing

member should it be desired that the system stick to the site on which it is placed." Claims 12 and 13 of EP'681 may also be referred to in this regard.

Further, in the last paragraph of column 8 and the first two paragraphs of column 9 of EP'681 the production of a corresponding patch is described and specific examples of pressure-sensitive adhesives for use in the layers 14 and 18 (polyacrylate or polyvinylethyl ether blend) are provided.

Since the drug releasing member of the device of EP'681 fails to be self-adhesive, it is self-evident that this member does not retain its original adhesive strength after application of the drug on the side that is to come into contact with the skin as recited in, e.g., present independent claim 40.

For at least all of the foregoing reasons, a rejection of the claims submitted herewith under 35 U.S.C. § 103(a) over EP'681 is without merit.

Response to Rejection under 35 U.S.C. § 103(a) over BAKER

Claims 1, 2, 5-8, 10-12, 16 and 26 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BAKER.

Applicants respectfully disagree with the Examiner in this regard as well. In particular, it is again pointed out that both the cancelled claims and the claims submitted herewith recite that the matrix of the present invention is self-adhesive. BAKER neither teaches nor suggests a self-adhesive matrix and for this reason alone, is unable to render obvious the subject matter of any of the claims submitted herewith.

Specifically, the controlled transdermal delivery system for nicotine disclosed by

BAKER comprises an impermeable backing layer, a polyurethane matrix layer which contains nicotine and an adhesive skin-contacting member. The adhesive skin-contacting member holds the patch in contact with the skin of the wearer and may, for example, be an acrylic- or silicone-based adhesive or polyisobutylene, an amine-resistant adhesive being preferred. See, e.g., abstract, col. 2, lines 55-59, col. 3, lines 1-18, col. 4, lines 32-45, col. 6, lines 9-14 and the claims of BAKER.

Since the polyurethane matrix layer of the device of BAKER fails to be self-adhesive, it is self-evident that this member does not retain its (lacking) original adhesive strength after application of the drug on the side that is to come into contact with the skin as recited in, e.g., present independent claim 40.

For at least all of the foregoing reasons, a rejection of the claims submitted herewith under 35 U.S.C. § 103(a) over BAKER is without merit.

Response to Rejection under 35 U.S.C. § 103(a) over HARALAMBOPOULOS

Claims 1, 3, 6-10, 12, 16-20, 23, 24 and 26 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over HARALAMBOPOULOS. The rejection appears to mainly rely on the embodiment of Figure 12 of HARALAMBOPOULOS, i.e., a process wherein a bioactive liquid is printed on the adhesive layer of a medical tape using conventional flexographic printing techniques as generally discussed in the passage from column 10, line 53 to col. 11, line 43 of HARALAMBOPOULOS.

Applicants respectfully disagree with the Examiner in this regard as well. In particular, while the cited passage of HARALAMBOPOULOS is quite specific regarding the

composition and properties of the bioactive liquid and the printing process, it does not provide any information whatsoever as to the composition and the properties of the adhesive matrix 2 of Figure 12. In fact, the only passage regarding the composition of the adhesive is found in col. 6, lines 14-20 of HARALAMBOPOULOS which states:

> A variety of adhesives may be used in the manufacture of such pressure sensitive adhesive tapes, for example, acrylic and methacrylic ester homo-or copolymers, butyl rubber based systems, silicones, urethanes, vinyl esters and amides, olefin copolymer materials, natural or synthetic rubbers, and the like, including hot-melt adhesives (See, for example, U.S. Pat. No. 5,387,450).

This very broad and unspecific disclosure which does not even indicate which of the cited adhesives, if any, would be suitable for the printing process discussed with reference to Figure 12 of HARALAMBOPOULOS clearly does not motivate one of ordinary skill in the art to pick a polyurethane as material for the adhesive matrix 2.

In this regard, it is further pointed out that the drug containing polyurethane matrices of EP'681 and BAKER are not self-adhesive, which may be taken as an indication that polyurethanes are not suitable for the purpose of the printing process of HARALAMBOPOULOS.

Further, while HARALAMBOPOULOS does not provide any specific information as to the degree of adhesiveness of the adhesive matrix after the printing process, the fact that HARALAMBOPOULOS recommends to use half-tone printing in which the entire surface of the adhesive matrix is not covered with the bioactive liquid but instead, a pattern of dots is applied to cover a portion of the adhesive matrix, e.g., approximately 25 % (see col. 11, next-to-last line to col. 12, line 7 of HARALAMBOPOULOS), is at least a strong indication that the adhesive properties of the matrix are deteriorated by the printing process

(wherefore a substantial portion of the surface of the matrix which is to come into contact with the skin must not come into contact with the bioactive liquid). In other words, HARALAMBOPOULOS also fails to teach or suggest that the adhesive matrix 2 retains its original adhesive strength after application of the bioactive liquid on the side that is to come into contact with the skin as recited in, e.g., present independent claim 40.

For at least all of the foregoing reasons, a rejection of the claims submitted herewith under 35 U.S.C. § 103(a) over HARALAMBOPOULOS is without merit.

Discussion of Secondary References

Several of the cancelled claims are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over a combination of one of the teachings of EP'681, BAKER and HARALAMBOPOULOS with the teachings of MIRANDA, GUERET or KENNDOFF. Applicants respectfully submit that none of these secondary references is able to cure the deficiencies of EP'681, BAKER and HARALAMBOPOULOS set forth above.

Specifically, the contact adhesive layer 14 of the drug delivery device of MIRANDA is provided with a drug by means of a source layer 13 from the side which is opposite to the side which is intended for skin contact (see, e.g., col. 5, lines 30-45 in combination with Fig. 1). In column 5, lines 58-63 of MIRANDA it is also mentioned that alternatively, the inner surface of the contact layer may be treated with the drug and thus itself serve as the source layer for purposes of drug deposition and that still another alternative is to use an adhesive layer that has a porous surface, enabling drug to be printed "into" the surface pores.

It is unclear from this statement whether the printing "into" the pores of the surface of the contact layer is to take place from the inner surface or from the skin contacting surface. It is even less clear how such a printing "into" the pores is to be accomplished.

At any rate, by emphasizing the application of the drug to the inner surface of the contact layer and the merely theoretical alternative of the printing of the drug into the pores of the contact layer MIRANDA makes it clear to one of ordinary skill in the art that applying the drug directly to the skin contacting surface of the contact layer is not desirable, thereby even teaching away from the present invention.

It further is noted that MIRANDA, while disclosing a number of materials which might be suitable for use in the contact adhesive layer (and the anchor layer), uses only two of these materials in the Examples, i.e., polyisobutylene and a blend of isobutylene and polybutene.

The cleansing treatment patch of GUERET includes a polymeric matrix which includes a cosmetically active compound and at least one water-absorbent compound. GUERET fails to teach or suggest that the cosmetically active compound in dissolved or liquid form is applied to the skin-contacting side of the polymeric matrix, let alone that after a corresponding application of the cosmetically active compound the skin-contacting side of the matrix remains self-adhesive.

According to GUERET, the preferred method of incorporating the cosmetically active compound in the polymeric matrix is by homogeneously dispersing the compound in particulate form in the matrix. See, e.g., col. 4, lines 35-40.

Further, regarding the materials for the polymeric matrix, there is very little

information provided by GUERET. Specifically, according to col. 6, lines 1-5 of GUERET the polymeric matrix preferably includes a silicone adhesive and more preferably, the polymeric matrix includes a polyacrylic or polyvinyl adhesive, such as a self-adhesive acrylic polymer sold by the company MAPEI, S.p.A. In the only example of GUERET the adhesive is a self-adhesive acrylic polymer (see table at the top of column 10).

For at least all of the foregoing reasons, GUERET neither teaches nor suggests applying the cosmetically active compound disclosed therein in dissolved or liquid form to the skin-contacting side of the polymeric matrix, let alone that after a corresponding application of the active ingredient the skin-contacting side of the matrix remains self-adhesive.

KENNDOFF relates to a wound dressing based on a (self-adhesive) hydrophilic polyurethane gel foam. KENNDOFF does not recommend the presence of any active ingredient in the polyurethane gel foam. Specifically, at column 6, lines 40-45 of KENNDOFF it is stated that the gels may, where appropriate, contain additives known per se from polyurethane chemistry such as, for example, fillers and chopped fibers with an inorganic or organic basis, metal pigments, surface-active substances or liquid extenders such as substances with a boiling point above 150°C. At column 7, lines 14-20 of KENNDOFF it is further stated that the fillers and additives can be selected from the customary class of substances, particularly advantageous being dyes, pigments, light stabilizers, preservatives, perfumes, substances with antimicrobial activity, other active substances such as substances with a cooling effect or those which promote blood flow or generate a sensation of warmth.

None of the compositions of the Examples of KENNDOFF contains any active ingredient.

Regarding the incorporation of additives and fillers into the polymeric matrix, KENNDOFF makes it clear that the preferred method comprises mixing the fillers and additives with the starting materials for the production of the polyurethane. In this regard, col. 8, line 63, to col. 9, line 24, col. 13, lines 5-35 and col. 16, line 44, to col. 17, line 5 of KENNDOFF may, for example, be referred to.

To sum up, also KENNDOFF neither teaches nor suggests applying an active ingredient, if any, in dissolved or liquid form to the skin-contacting side of the polymeric matrix, let alone that after a corresponding application of the active ingredient the skin-contacting side of the matrix remains self-adhesive.

Applicants respectfully submit that for at least all of the foregoing reasons, even a combination of the teachings of any one of EP'681, BAKER and HARALAMBOPOULOS, with the teaching of any one of MIRANDA, GUERET and KENNDOFF is unable to render obvious the subject matter of any of the claims submitted herewith, wherefore a rejection of these claims under 35 U.S.C. § 103(a) over any of these documents and combinations thereof is unwarranted.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, which action is respectfully requested. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to

contact the undersigned at the telephone number below.

Respectfully submitted,
Michael SCHINK et al.

Neil F. Greenblum
Reg. No. 28,394

Heribert F. Muensterer
Reg. No. 50,417

November 20, 2006
GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
(703) 716-1191